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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,740	06/23/2000	Markus Pompejus	BGI-126CP	1632

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EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/602,740	POMPEJUS ET AL.
	Examiner Kathleen M Kerr	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 25 October 2002.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,4-17,25-29,31-34,36 and 37 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 1,4-6,10-14,16,17,25-28 and 31-33 is/are allowed.

6) Claim(s) 7-9,29,34,36 and 37 is/are rejected.

7) Claim(s) 15 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> .	6) <input type="checkbox"/> Other: _____.

## **DETAILED ACTION**

### *Application Status*

1. In response to the previous Office action, a first Office action on the merits (Paper No. 11, mailed on April 22, 2000), Applicants filed a response and amendment received on October 25, 2002 (Paper No. 14). Said amendment amended the specification and Claims 1, 4-9, 15, 25, 29, 34, 36, and 37 and cancelled Claims 2, 3, 18-24, 30, 35, and 38. Thus, Claims 1, 4-17, 25-29, 31-34, 36, and 37 are pending in the instant Office action and will be examined herein.

### *Priority*

2. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application Nos. 60/141,031, filed on June 25, 1999, 60/143,208, filed on July 9, 1999, and 60/151,572, filed on August 31, 1999, as requested in the declaration and the first lines of the specification.

3. As previously noted, without certified copies of the foreign applications whose foreign priority has been requested (27 German applications), priority cannot be granted. Applicants have noted that certified copies would be filed upon issuance of a patent. Thus, foreign priority is herein NOT granted. Acknowledgment is made of applicant's claim for foreign priority based on applications (27 total) filed in Germany.

### *Information Disclosure Statement*

4. The information disclosure statement filed on October 25, 2002 (Paper No. 13) has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy.

***Withdrawn - Objections to the Specification***

5. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicants' amendment.
6. Previous objection to the title for not adequately describing the claimed subject matter is withdrawn by virtue of Applicants' amendment to the title.
7. Previous objection to the specification for missing Appendix A and Appendix B is withdrawn. These papers were discovered in the filed and appropriately entered so as to be a part of the specification as requested.

***Maintained - Objections to the Specification***

8. Previous objection to the specification for being confusing in its description of SEQ ID NOs: 1/2 as described in Table 1 is maintained. Applicants attempted to amend Table 1; however, this amendment could not be entered. An entire replacement page must be submitted to affect the proposed changes to the specification.

***Withdrawn - Claim Objections***

9. Previous objection to Claims 1-17 and 25-38 for containing non-elected subject matter is withdrawn by virtue of Applicants' amendment.
10. Previous objection to Claim 2 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claim.

11. Previous objection to Claim 30 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn by virtue of Applicants' cancellation of said claim.

***Maintained - Claim Objections***

12. Previous objection to Claim 15 under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is maintained. Applicants argue that the deletion of the term "modulation" from the instant claim now renders the claim properly further dependent. This is not the case. All host cells will naturally produce "fine chemicals" based on the broad definition of the term. Perhaps the claim could further limit if the expression of the nucleic acid molecule directly resulted in the production of a particular fine chemical. But, as amended, all host cells produce fine chemicals so this phrase cannot further limit the subject matter of the parent claim.

***Withdrawn - Claim Rejections - 35 U.S.C. § 112***

13. Previous rejection of Claims 2, 8, and 34 under 35 U.S.C. § 112, second paragraph, as being indefinite for the unclear abbreviation "SMP" is withdrawn by virtue of Applicants' amendments to the claims.

14. Previous rejection of Claims 8 and 34 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "stringent conditions" is withdrawn by virtue of Applicants' amendment entering the hybridization conditions directly into the claims.

15. Previous rejection of Claims 25-33 under 35 U.S.C. § 112, second paragraph, as being indefinite for the reference to the “vector of claim 12” is withdrawn by virtue of Applicants’ amendment to have Claim 25 depend from Claim 11.

16. Previous rejection of Claim 38 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term “regulatory region” is withdrawn by virtue of Applicants’ cancellation of said claim.

17. Previous rejection of Claims 5 and 6 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants’ amendment adding functional limitations to the instant claims.

18. Previous rejection of Claims 36 and 37 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants’ amendment to said claims.

19. Previous rejection of Claim 38 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicants’ cancellation of said claim.

20. Previous rejection of Claim 6 under 35 U.S.C. § 112, first paragraph, scope of enablement, because the specification, while being enabling for polynucleotides with at least, for example, 90% sequence identity to a polynucleotide which encodes SEQ ID NO:2, does not reasonably provide enablement for polynucleotides with such low sequence identity as 50%, is withdrawn by virtue of Applicants’ amendment.

21. Previous rejection of Claim 35 under 35 U.S.C. § 112, first paragraph, enablement, is withdrawn by virtue of Applicants' cancellation of said claim.

***Maintained - Claim Rejections - 35 U.S.C. § 112***

22. Previous rejection of Claim 29 under 35 U.S.C. § 112, second paragraph, as being indefinite for particular genus/species names being is maintained in part. Some of Applicants' amendments have obviated the objections; each item from the previous Office action is noted in turn below:

- a) the name "*Corynebacterium lilium*" has been corrected appropriately
- b) the spelling of "*Brevibacterium parrafinoliticum*" is now correct
- c) *Brevibacterium divaricatum* and *Brevibacterium lactofermentum* have been deleted
- d) *Brevibacterium healii*, *Brevibacterium ketoglutamicum*, and *Brevibacterium parrafinoliticum* are synonyms of the same species, *Rhodococcus erythropolis*, Applicants noted that they deleted the *healii* and *ketoglutamicum* species, but this is not the case. **Two of *healii*, *ketoglutamicum*, and *parrafinoliticum* must be deleted to avoid redundancy in the Markush group.**
- e) *Corynebacterium acetoglutamicum*, *Corynebacterium fujikense*, and *Corynebacterium nitrilophilus* have indeed been identified in the ATCC database. *Corynebacterium butanicum* has been deleted from the claims.

Appropriate correction for item d above is required.

23. Previous rejection of Claims 7, 8 and 34 under 35 U.S.C. § 112, first paragraph, written description, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue that based on the written description guidelines, the fragment language of Claim 7 is adequately described. The Examiner disagrees. As previously noted, "Claim 7 is

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drawn to DNA **comprising** at least a 15-mer fragment of SEQ ID NO:1" (emphasis added).

Thus, any nucleic acid molecule containing at least 15 consecutive nucleotides of SEQ ID NO:1 would be encompassed by the instant claim. The specification describes only nucleic acid molecules encoding 6-phosphoglucolactonases and having the denoted structure.

Applicants present no arguments particular to Claim 8 and its hybridization language in the absence of functional language. As previously noted, "Claim 8 is drawn to DNA that hybridizes to any of the foregoing DNAs". As above, the specification describes nucleic acid molecules that hybridize to the noted sequence and encode 6-phosphoglucolactonases but does not adequately describe nucleic acid molecules that hybridize but encode proteins of different functions.

24. Previous rejection of Claims 7, 8 and 34 under 35 U.S.C. § 112, first paragraph, scope of enablement, is maintained. Applicants' arguments have been fully considered but are not deemed persuasive.

Applicants argue that based on the written description guidelines, the fragment language of Claim 7 is enabled with limited experimentation based on the skill in the art. The Examiner disagrees. As previously noted, "Claim 7 is drawn to DNA **comprising** at least a 15-mer fragment of SEQ ID NO:1" (emphasis added). Thus, any nucleic acid molecule containing at least 15 consecutive nucleotides of SEQ ID NO:1 would be encompassed by the instant claim. Without a function associated with the claimed nucleic acid molecule, one of skill in the art would be unaware how to use the claimed invention. Testing of numerous possible activities would be required, without predictability of the function (i.e., how to use the product).

Applicants present no arguments particular to Claim 8 and its hybridization language in the absence of functional language. As previously noted, "Claim 8 is drawn to DNA that hybridizes to any of the foregoing DNAs". As above, the specification enabled the use of nucleic acid molecules that hybridize to the noted sequence and encode 6-phosphoglucolactonases with limited, predictable experimentation but does not adequately enable nucleic acid molecules that hybridize but encode proteins of different functions without undue experimentation.

***Withdrawn - Claim Rejections - 35 U.S.C. § 102***

25. Previous rejection of Claim 9 under 35 U.S.C. § 102(b) as being anticipated by Ma *et al.* is withdrawn by virtue of Applicants' amendment.

***Maintained - Claim Rejections - 35 U.S.C. § 102***

26. Previous rejection of Claims 7 and 8 under 35 U.S.C. § 102(b) as being anticipated by Marra *et al.* is maintained. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons.

Applicants argue that Marra *et al.* do not teach a polynucleotide sequence comprising a fragment of SEQ ID NO:1 or the complement thereof. Clearly, in the alignment previously attached, nucleotides 366-386 inversely align to SEQ ID NO:1 from nucleotides 792-812. Thus, Marra *et al.* meet all the limitations of the instant claims. The alignment Applicants provided does not assess the complementarity of the inverse sequences.

***Withdrawn - Double Patenting***

27. Previous comments concerning the possible double patenting issues of Claims 2 and 3 are moot in view of Applicants' cancellation of said claims.

**NEW REJECTIONS**

***Claim Rejections - 35 U.S.C. § 112***

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

28. Claims 36 and 37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if the non-disrupted nucleic acid molecule only has the claimed functional limitation (i.e., if the disruption knocks out the function) or if both the undisrupted and disrupted nucleic acid molecule has the claimed functional limitation. Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

29. Claim 9 is rejected under 35 U.S.C. § 112, first paragraph, written description, for the same reasons noted previously and above for Claims 7 and 8.

30. Claim 9 is rejected under 35 U.S.C. § 112, first paragraph, scope of enablement, for the same reasons noted previously and above for Claims 7 and 8.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

31. Claim 9 is rejected under 35 U.S.C. § 102(b) as being anticipated by Marra *et al.* for the reasons noted previously and maintained above for Claim 7 since the remainder of the Marra *et al.* sequence can be considered heterologous to the fragment of SEQ ID NO:1 embedded within.

***Summary of Pending Issues***

32. The following is a summary of the issues pending in the instant application:

- a) No foreign priority documents have been filed to obtain the earliest effective filing date sought by Applicants.
- b) The specification stands objected to for being confusing in its description of SEQ ID NOs: 1/2 as described in Table 1.
- c) Claim 15 stands objected to under 37 C.F.R. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.
- d) Claim 29 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for having redundant terms in the Markush group.
- e) Claims 36 and 37 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.
- f) Claims 7-9 and 34 stand rejected under 35 U.S.C. § 112, first paragraph, written description.
- g) Claims 7-9 and 34 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.
- h) Claims 7-9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Marra *et al.*

***Conclusion***

33. Claims 1, 4-6, 10-14, 16, 17, 25-28, and 31-33 are allowed in the Office action; Claims 7-9, 15, 29, 34, 36, and 37 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone

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numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



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